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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/835,501	04/16/2001	Tyler B. Parr		5399

7590 06/02/2004  
Tyler Parr, Ph.D.  
P.O. Box 371  
Chula Vista, CA 91912

EXAMINER

JOYNES, ROBERT M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/835,501	Applicant(s) PARR, TYLER B.	
	Examiner Robert M. Joynes	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Receipt is acknowledged of applicants Amendment and Response filed on March 16, 2003.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims recite that growth hormone release is augmented by a *chemical synergy* between acetyl-L-carnitine and L-ornithine. The instant specification has not describe this synergy in such a way to reasonably convey to one skilled in the art that the inventor had possession of this claimed synergy at the time the application was filed.

First, the Examiner would like to point out that the Measurement Evidence of Efficacy section of the instant Specification shows no difference between either the ornithine or the carnitine by themselves when compared to the control. Neither of the compounds is better than the control. Ornithine is known to augment growth hormone levels (See White, U.S. Patent No. 6346264). It is perplexing how ornithine now has no effect on growth hormone at the same levels described in the prior art.

Second, the increase that is shown in the Experimental data that is in the Specification is due to the increased amounts of ornithine. The data shows that at 500 mg each (ornithine and carnitine alone) growth hormone levels are at 0.55 ng/ml. Then 500 mg of carnitine is combined with 25 mg of ornithine to produce growth hormone levels of 1.25 ng/ml. This figure is not statistically significant when compare to the two components alones. Further, as you increase the amount of ornithine from 25 mg to 35 and 45 mg the growth hormone levels increase. This data shows two things: first, there is no evidence to show what the growth hormone levels are for ornithine alone at a dosage of 25, 35 and 45 mg; and second, that the growth hormone levels increase is caused by the ornithine being that the carnitine levels remained the same through the experiment. The carnitine therefore, has not been shown to have any effect on growth hormone levels.

Finally, it is the position of the Examiner that is no synergy is evidenced because even at high concentrations of ornithine alone, no significant effect is shown. The applicant has failed to show that a synergy is occurring between the ornithine and the carnitine. Applicant has only shown that increased concentrations of ornithine increase the growth hormone levels. This effect is already known in the art at similar concentrations. Without data that shows what effect ornithine has on growth hormones at doages of 25, 35 and 45 mg, it is difficult to understand that a synergy is actually taking place between the two components.

Therefore, the instant claims lack the proper written description to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

***Claim Rejections - 35 USC § 103***

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giampapa (US 5895652). Giampapa teaches a nutritional supplement comprising both acetyl-L-carnitine and ornithine (Col. 5, line 5 – Col. 10, line 21). Ornithine is taught as a growth hormone formula (Col. 6, lines 42-44). The supplement is designed to maximize the body's inherent biochemical pathways to thereby limit damage otherwise caused by deficiencies during normal aging (Col. 4, lines 24-67).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to combine L-ornithine with acetyl-L-carnitine to maintain proper biochemical levels in the body as well as to augment growth hormone levels. The reference teaches that ornithine is a growth hormone augmenting substance. The reference further teaches that acetyl-L-carnitine is combined with ornithine to maximize biochemical levels in the body. Therefore it would have been obvious to combine the

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two as a supplement to treat the body and augment growth hormone levels. In addition, there is no evidence in the data present in the instant application to support any unexpected or superior results. As stated above, the data presented does not show any synergy between the two components and any increase in growth hormone levels is due to the increasing levels of ornithine.

One of ordinary skill in the art would have been motivated to do this to maximize the biochemical levels in the body so as to avoid any deficiency during the normal aging process as well as to maintain proper metabolism and function of the human body at time of the daily biocycle when the need for such components exists.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-6 have been considered but are moot in view of the new ground(s) of rejection. Due to the new grounds for rejection, this action is deemed non-final.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joyner whose telephone number is (571) 272-0597. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

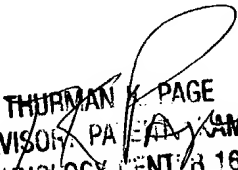
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert M. Joynes  
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